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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/506,331 | 09/02/2004 | Christopher Daly | 22409-00050-US | 8801 |
| 30678 7590 06/27/2008 CONNOLLY BOVE LODGE & HUTZ LLP 1875 EYE STREET, N.W. SUITE 1100 WASHINGTON, DC 20036 | | | | |
| EXAMINER | | | | |
| PATTON, AMANDA K | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3762 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 06/27/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,331

Applicant(s)

DALY ET AL.

Examiner

Amanda Patton

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 30, 2008 has been entered.

In response to the amendments to claims 41 and 51, the rejections of those claims under 35 U.S.C. 112, second paragraph have been withdrawn. Currently claims 39-69 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-41, 43-49, 55-57, 59-62, and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. (US Pat. 6,648,914, as previously cited).

Regarding **claims 39-40, 47, 55-56, and 64**, Berrang discloses the claimed invention including: a housing configured to be implanted in a recipient (e.g. housing sections 2 and 3) comprising receiver electronics (e.g. RF link; Col. 4, line 55 and external and internal coil; Col. 5, lines 59-60) and stimulator electronics (e.g. electronics; Col. 3, line 34) configured to output one or more stimulation signals (e.g. Col. 4, lines 25-38); and a first electrode assembly (e.g. electrode array 10) having first and second longitudinally extending continuous regions, wherein the first region is connected to the housing along an axis of rotation of the housing (e.g. Figure 1, wherein the axis of rotation of the housing is about the pliable bridge 6) and wherein the second region is configured to be at least partially implanted into a cochlear of the recipient to deliver stimulation to the cochlea; and wherein the first region and the housing are configured such that following implantation of the second region into the cochlea, the housing is rotatable between a first and second implant orientations about said axis of rotation of the housing such that the second region implanted in the cochlea remains substantially stationary during the rotation; the location of the receiver electronics are different in the first and second implant orientations, and an external component having a transmitter coil configured to transmit signals from the external component to the receiver coil (e.g. external part 31 comprising coil 53).

Due to the flexible nature of the electrode array and the pliable bridge connecting the two portions of the housing together the housing is capable of rotating between a first and second implant orientation when the patient's head grows, etc. Examiner wishes to note that the claim does not mention how much of a difference there must be between the first and second implant orientations, and thus any small rotation that occurs when the patient's head grows fulfils the limitation of the claims.

Regarding **claims 41 and 57**, Berrang additionally teaches a housing comprising a lateral surface wherein the first region of the first electrode assembly is connected to the lateral surface of the housing most proximate the cochlea when the housing is in the first implant orientation (e.g. surface of pliable bridge 6 wherein junction 16 is placed; Figure 1).

Regarding **claims 43-44 and 59-60**, Berrang additionally teaches that the housing is at least partially formed from resiliently flexible material wherein the region adjacent one or more of the edges is resiliently deformable (e.g. pliable bridge 6).

Regarding **claims 45 and 61**, Berrang additionally teaches a housing that is substantially symmetrically about a plane that is parallel to the longitudinal axis of the first region of the electrode array.

Regarding **claims 46 and 62**, Berrang additionally teaches in the alternate embodiments (e.g. Figure 17) a housing configuration that is substantially symmetrical about a plane that is perpendicular to the longitudinal axis of the first region of the electrode array.

Regarding **claim 48-49**, Berrang additionally teaches an external component (e.g. external part 51; Figure 9), and wherein the implantable housing further comprising a receiver coil configured to receive RF signals from the external component (e.g. coil 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang.

Regarding **claims 42 and 58**, Berrang discloses the claimed invention but does not disclose expressly the placement of the first region of the electrode array that is connected to a surface that is adjacent to a lateral surface that is most proximate the cochlea. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the housing as taught by Berrang with the placement of the first region of the electrode array that is connected a surface that is adjacent to a lateral surface that is most proximate the cochlea, because Applicant has not disclosed that this placement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrode placement as taught by Berrang, because it provides proper insertion into the cochlea and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Berrang. Therefore, it would have been an obvious matter of design choice to modify Berrang to obtain the invention as specified in the claims.

Claims 50-51, 63, and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang in view of Faltys et al. (US Pat 6,272,382, as previously cited, hereafter "Faltys '382").

Regarding **claims 50 and 65**, Berrang does not expressly teach electronics configured to allow transcutaneous bidirectional data transfer between the implantable component and the external component. Faltys '382 teaches that it was known in the art to use a receiver coil that is part of an RF link that allows both traditional transfer of data from the external headpiece coil and the implantable component 14 and back telemetry between the external headpiece coil 52

and the implantable component 14 (Col. 10, lines 20-27, and as shown through bidirectional arrows in Figure 1A-1E). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the bidirectional data transfer of Faltys '382 in the device of Berrang, since such a modification would provide the system with the ability to communicate data between the implanted device and the external component for providing the predictable results of better stimulation based on implant feedback.

Regarding **claims 51 and 66**, Berrang does not expressly teach an external component comprising a microphone. Faltys '382 teaches that it was known in the art to use an external component in cochlear implant system comprising a microphone (e.g. microphone 104 located in headpiece (HP) 106; Col. 7, lines 60-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the external components of Faltys '382 in the device of Berrang since such a modification would provide the system with a smaller amount of electronics to implant for providing the predictable results of a smaller implant resulting in an easier implantation.

Regarding **claim 63**, Berrang does not expressly teach an external component comprising a microphone configured to receive an input sound and a signal processor configured to convert the inputted sound into a coded signal. Faltys '382 teaches that it was known in the art to use an external component in cochlear implant system comprising a microphone and a signal processor to convert the inputted sound into coded signal (e.g. microphone 107 and speech processor (SP) located in headpiece (HP) 106; Col. 7, lines 60-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the external components of Faltys '382 in the device of Berrang since such a modification would provide the system with a

smaller amount of electronics to implant for providing the predictable results of a smaller implant resulting in an easier implantation.

Claims 52-54 and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang in view of Carter et al. (US Pat. 6,205,360, as previously cited)

Regarding **claims 52 and 67**, Berrang does not teach an implantable component comprising a second electrode assembly. Carter teaches a second extra-cochlear electrode assembly 13 (e.g. Figure 1; Col. 6, lines 10-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a second extra-cochlear electrode array in the device of Berrang in order to provide the predictable results of a reference electrode not affected by stimulation in the cochlea.

Regarding **claims 53-54 and 68-69**, Berrang and Carter disclose the claimed invention but does not disclose expressly a second electrode assembly connected to a lateral surface of the housing opposing the first electrode assembly and substantially aligned with a longitudinal axis of the electrode array. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the second electrode array as taught by Berrang and Carter with the specific placement of the second electrode array, because Applicant has not disclosed that the array placement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrode array arrangement as taught by Berrang and Carter, because it provides proper electrode array placement and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Berrang and Carter.

Therefore, it would have been an obvious matter of design choice to modify Berrang and Carter to obtain the invention as specified in the claims.

Response to Arguments

Applicant's arguments filed May 30, 2008 have been fully considered but they are not persuasive. Regarding Applicant's argument that Berrang does not disclose the limitation "and the location of said receiver electronics are different in the first and second implant orientations" of claim 39, Examiner disagrees. It is the Examiner's position that the device of Berrang can be placed in a first implant orientation (e.g. before the patient's head grows) and a second implant orientation (e.g. after some elapsed time when the patient's head has grown) and, since the two sections of the housing are separated by a pliable, flexible bridge, the location of the receiver electronics will be different in the first and second implant orientations. Examiner wishes to note that the claims do not preclude the different locations to be only small distances from each other, as no mention is made in the claims of the amount of movement between the two implant positions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AKP/
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762